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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,298	07/16/2007	Rosario Rizzuto	026073-00008	8068
4372	7590	06/30/2009		
ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
			NOTIFICATION DATE 06/30/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/594,298	RIZZUTO ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-93 is/are pending in the application.
- 4a) Of the above claim(s) 51-54,60-62,67,68 and 70-93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55-59,63-66 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/26/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction/Election

1. Applicant's election without traverse of Group II (claims 55-69) and proteins that link plasmatic membrane receptors as the species of regulating proteins, and a receptor as the species of heterologous proteins/cellular effectors in the reply filed on 04/20/2009 is acknowledged.
2. Applicants' amendments filed on 09/26/2006 and 07/16/2007 are entered. Claims 51-93 are pending. Claims 55-59, 63-66, and 69 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species.

Information Disclosure Statement

3. The information disclosure statement filed on 09/26/2006 has been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action. It's noted that some of the cited references have not been submitted and thus are not considered.

Drawings

4. The drawings filed on 09/26/2006 are accepted by the Examiner.

Priority

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5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections—35 USC § 112, 2nd paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 64-66 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 is indefinite because it recites "a heterologous native or chimeric protein". If a protein is heterologous, it cannot be "native". Claims 65 and 66 are rejected as dependent claims from claim 64.

Claim 69 recites the limitation "said cellular receptor" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections—35 USC § 102 (b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 55-59 and 63 are rejected under 35 U.S.C. 102 (b) as being anticipated by Poul et al. (Journal of Biomolecular Screening 7 (1):57-61, 2002).

Poul et al. teach a cellular aequorin-based high throughput screening of G protein-coupled receptor (GPCRs). CHO-K1 cells were transfected with a plasmid encoding the apoaequorin gene with a mitochondrial targeting signal and G α 16 (page 58, under Stable aequorin cell line). The CHO-K1 cells were also transfected with expression plasmids encoding three different human GPCRs, melanin-concentrating hormone type 1 receptor (MCH1), orexin type 2 receptor (O α 2), and serotonin type 2B receptor (5-HT $_{2B}$); page 58, under section of GPCRs in aequoscreen cell lines). The cells are loaded with the apoaequorin cofactor coelenterazine, diluted in assay buffer, and injected into plates containing the samples to be tested. The results were expressed as relative light units (Abstract; page 58, under the section of Aequorin assays).

Thus, the teachings of Poul et al. meet the limitations of claims 55-59 and 63.

Claim Rejections — 35 USC § 103(a)

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Poul et al. (Journal of Biomolecular Screening 7 (1):57-61, 2002).

Poul et al. teach a cellular aequorin-based high throughput screening of G protein-coupled receptor (GPCRs). CHO-K1 cells were transfected with a plasmid encoding the apoaequorin gene with a mitochondrial targeting signal and $G\alpha_{16}$ (page 58, under Stable aequorin cell line). The CHO-K1 cells were also transfected with expression plasmids encoding three different human GPCRs, melanin-concentrating hormone type 1 receptor (MCH1), orexin type 2 receptor (O_{x2}), and serotonin type 2B receptor ($5-HT_{2B}$); page 58, under section of GPCRs in aequoscreen cell lines). The cells are loaded with the apoaequorin cofactor coelenterazine, diluted in assay buffer, and injected into plates containing the samples to be tested. The results were expressed as relative light units (Abstract; page 58, under the section of Aequorin assays).

Poul et al. do not teach that a cell line of b) of claim 55 is previously engineered so as to express a heterologous native or chimeric protein as recited in claim 64.

However, it would have been obvious for one of skill in the art, as a choice, to transfect the cells first with an expression vector encoding a GPCR and to screen an agonist of the GPCR or chimeric GPCR using a cellular aequorin-based high throughput screening method taught by Poul et al. with a reasonable expectation of success. One would be motivated to do so because it is well within the skills of an artisan to either transfect the cells first with an expression vector encoding a GPCR or transfect the cells first with an expression vector encoding the apoaequorin gene with a mitochondrial

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targeting signal and G α 16.

12. Claims 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poul et al. (Journal of Biomolecular Screening 7 (1):57-61, 2002) in view of Langer et al. (Molecular Endocrinology 16(5):1089-1096, 2002).

Poul et al. teach a cellular aequorin-based high throughput screening of G protein-coupled receptor (GPCRs). CHO-K1 cells were transfected with a plasmid encoding the apoaequorin gene with a mitochondrial targeting signal and G α 16 (page 58, under Stable aequorin cell line). The CHO-K1 cells were also transfected with expression plasmids encoding three different human GPCRs, melanin-concentrating hormone type 1 receptor (MCH1), orexin type 2 receptor (O $_{x2}$), and serotonin type 2B receptor (5-HT $_{2B}$); page 58, under section of GPCRs in aequoscreen cell lines). The cells are loaded with the apoaequorin cofactor coelenterazine, diluted in assay buffer, and injected into plates containing the samples to be tested. The results were expressed as relative light units (Abstract; page 58, under the section of Aequorin assays).

Poul et al. do not teach that a cell line of b) of claim 55 is previously engineered so as to express a chimeric receptor as recited in claim 66.

Langer et al. teach construction of a chimeric human VPAC1/VPAC2 GPCR, expression of the chimeric receptor in CHO cells co-expressing aequorin, and measurement of VIP-mediated calcium increase by a functional assay based on the luminescence produced after coelenterazine oxidation (Abstract, page 1089, right column, the 2nd paragraph).

It would have been obvious for one of skill in the art, as a choice, to

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transfect the cells first with an expression vector encoding a GPCR or a chimeric GPCR and to screen an agonist of the GPCR or chimeric GPCR using a cellular aequorin-based high throughput screening method taught by Poul et al. with a reasonable expectation of success. One would be motivated to do so because (i). it is well within the skills of an artisan to either transfect the cells first with an expression vector encoding a GPCR or transfect the cells first with an expression vector encoding the apoaequorin gene with a mitochondrial targeting signal and $G\alpha 16$; (ii). a chimeric receptor, such as a chimeric GPCR can be used to study the structure/activity of a chimeric receptor as taught by Langer et al. (Table 1, Fig. 2, page 1089, right column, the 2nd paragraph).

Claim Objection—Minor Informalities

13. Claims 55, 58, and 65 are objected to because of the following minor informalities: (i). claim 55 is objected to because it recites, at the end of part (a), "and/or a signal sequence"; (ii). claims 58 and 65 are objected to because they recite non-elected species. Appropriate correction is required.

Conclusion

14. No claims are allowed.

Advisory Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.

June 25, 2009